

## REMARKS

The pending Office Action addresses claims 1-27. Claims 26 and 27 were withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention. The Examiner withdraws claims 3-20 and 23-25 from further consideration pursuant 37 CFR § 1.142(b). Applicants preserve their right for rejoinder of the withdrawn claims and full examination for patentability under 37 CFR § 1.104 of the same. Claims 1, 2, 21, and 22 are rejected. Reconsideration of the rejection of claims 1, 2, 21, and 22 is respectfully requested in view of the following remarks.

### *Amendments to the Specification*

Applicants replace the sentence at page 26, lines 6-9 of the original application with the amended sentence above to fix the typographical errors highlighted by the Examiner in the pending Office Action. Specifically, references to microparticles 12<sup>'''</sup> were replaced by references to microparticles 12<sup>'''</sup> to bring the description in agreement with the drawings. FIG. 2, which the sentence at page 26, lines 6-9 is directed toward, includes microparticles 12<sup>'''</sup> as opposed to microparticles 12<sup>'''</sup>. No new matter is added.

### *Amendments to the Claims*

Although claim 17 is withdrawn, Applicants amend claim 17 to fix a typographical error. No new matter is added.

### *Election/Restrictions*

In a Restriction Requirement dated December 10, 2007, the Examiner required Applicants to elect one of Species A-H. In a response to the Restriction Requirement, dated April 4, 2008, Applicants elected Species H (treating an infection below the surface of the body tissue by administering at least one therapeutic molecule or ion by directing the therapeutic molecule or ion into at least one microconduit, thereby delivering the therapeutic molecule or ion through the surface of the body tissue) *with traverse*. The Examiner considers the restriction to Species H proper, and as a result withdraws claims 3-20 and 23-25 from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected species. The Examiner contends that there is no allowable generic or linking claim.

While Applicants respectfully disagree with the Examiner's position, Applicants request that their right to rejoinder of the withdrawn claims be preserved so that a request for rejoinder and full

examination for patentability under 37 CFR §1.104 of the withdrawn claims be permitted after the grant of an allowable generic or linking claim. Applicants consider each of claims 1, 2, 21, and 22 to be either a generic or a linking claim.

### ***Objection to the Drawings***

The Examiner objects to the drawings as failing to comply with 37 CFR § 1.84(p)(5) because they include a reference character not mentioned in the description. More particularly, the Examiner notes that the drawings include reference character 12<sup>'''</sup> but that the description fails to include reference character 12<sup>'''</sup>. Applicants amend the specification to correct a typographical error in which microparticles 12<sup>'''</sup> in the sentence at page 26, lines 6-9 of the original application were supposed to have been microparticles 12<sup>'''</sup>. Accordingly, the specification has been amended to correct this issue. Applicants respectfully request that the Examiner withdraw this objection.

### ***Nonstatutory Double Patenting Rejection***

The Examiner rejects claims 1, 2, 21, and 22 pursuant to the judicially created doctrine of obviousness-type double patenting in light of claims 1-74 of U.S. Patent No. 6,706,032 of Weaver et al. ("Weaver"). Applicants rely on the terminal disclaimer related to Weaver submitted herewith to obviate this rejection.

### ***Rejections Pursuant to 35 U.S.C. § 102(e)***

The Examiner rejects claims 1 and 2 pursuant to 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,010,478 of Bellhouse et al. ("Bellhouse"). The Examiner argues that Bellhouse discloses a method of modifying or manipulating body tissue as recited by Applicants. The Examiner also argues that Bellhouse teaches treating an infection by delivering a therapeutic molecule or ion through the tissue. Applicants respectfully disagree.

Claim 1 is directed to a method of modifying or manipulating body tissue by forming at least one microconduit therein by accelerating a plurality of microparticles to a velocity that causes the microparticles to penetrate a region of a tissue surface upon impingement of the microparticles on the tissue surface, directing the microparticles towards the region of tissue surface, thereby causing the microparticles to penetrate the tissue, and *scissioning* the tissue with the impinging microparticles, thereby *forming a plurality of free microtissue particles*, and thereby *forming a microconduit*. While

Bellhouse does include teachings directed to a method for delivering particles, it fails to teach or even suggest a method in which scissioning the tissue with the impinging microparticles results in the formation of free microtissue particles and a microconduit.

Scissioning, as defined in the specification, involves both cutting and removing the small particles of cut tissue, either by the carrier medium or by attachment of the cut tissue particles to the cutting particles, whereby they are carried off by momentum transfer. (See paragraph 68 of the published application.) Once the tissue particles have been scissioned (cut and removed), the claimed microconduits are available for use. (See paragraph 69.) The microconduits remain open until the skin heals, which can be controlled by drugs. (See at least paragraphs 117 and 118.) Not only does Bellhouse fail to teach the formation of free microtissue particles and a microconduit by scissioning the tissue with the impinging microparticles; it *teaches against* such a method.

The method used in Bellhouse is purposely designed so that skin cells *are not* damaged and *are not* removed. More particularly, Bellhouse teaches a certain size, shape, and velocity of the microparticles so that the microparticles can be pushed (or perhaps travel) through the skin without causing *untoward damage*. (See col. 10, lines 17-35.) Bellhouse teaches “roughly spherical” particles that have an optimal size of at least about 10 to 15  $\mu\text{m}$ , and optimally substantially smaller than 10  $\mu\text{m}$  when delivering genes. (*Id.*) The optimal range of Applicants’ particles, on the other hand, is about 15 to 70  $\mu\text{m}$  and the shape of the particles is quite different. (See paragraphs 55, 123, and 159.) In Bellhouse, the round (roughly spherical) particles are designed to *not harm skin cells*. (Col. 10, lines 23-32.) In the present invention, on the other hand, irregularly sized “cutting” particles are specifically designed to *cut and remove tissue* upon contact. (See at least paragraphs 89, 104, and 123.) For instance, in Example 1 of the present application, the microparticles are characterized as “sharp, with size generally ranging between about 15  $\mu\text{m}$  and about 20  $\mu\text{m}$ , with some 30  $\mu\text{m}$  outliers.” (Paragraph 159.) A person having ordinary skill in the art would understand that the size and shape of the Bellhouse particles are *not* conducive to scissioning because they are generally smaller (optimally at least about 10 to 15  $\mu\text{m}$  vs. optimally from about 15 to 70  $\mu\text{m}$ ) and smoother (“roughly spherical” particles vs. irregularly sized “cutting” particles) than the particles described in the present invention. The particles of Bellhouse *teach against* the claimed invention because the particles of Bellhouse are designed to not cause *untoward damage* to the skin.

In addition to teaching particles that are not sized and shaped to cause scissioning, Bellhouse also fails to teach a velocity of the particles that cause scissioning. In fact, the velocity at which the microparticles are delivered to tissue in Bellhouse varies dramatically from the velocity at which the microparticles are delivered in the present invention. In Bellhouse, a "supersonic delivery" (having a velocity ranging from about 200 to about 3000 m/sec) is used to push the round particles through the soft skin surface and embed the particles (coated with drug) therein. (See col. 10, lines 17-35; *see also* col. 7, lines 36-43.) Because of the high velocity and momentum, the high energy particles can be pushed (or perhaps travel) through the skin, much like a needle puncture. (*Id.*) The resiliency of the skin then causes the closure of the hole formed as each particle pass through the skin layers. The skin *is not removed*; it is simply pierced by the impact of the round particles.

The present invention, on the other hand, teaches subsonic delivery velocities, such as 1 m/sec. (See, e.g., paragraph 55; *see also* the Examples.) This is vastly different from the supersonic velocities (Mach 2-8) taught in Bellhouse. (Col. 7, lines 36-43; *see also* col. 10, lines 17-35.) Allowing the particles to strike at a subsonic speed as taught in the present invention allows the particles to cut and remove, i.e., scission, tissue from the skin to form the microconduit. (Paragraph 55.) Once the tissue particles have been scissioned (cut and removed) the claimed microconduits are available for use. (See paragraph 69.) The microconduits remain open until the skin heals, which can be controlled by drugs. (See at least paragraph 117 and 118.) While the velocities taught in Bellhouse are conducive for allowing microparticles to be pushed (or perhaps travel) through the skin, they are not conducive to scissioning because they do not cut or remove tissue from the skin. Any potential hole formed by the Bellhouse blasting method seals right behind the particle as it passes through the skin layers. Tissue is *cut and removed* in the present invention, but it is *not cut or removed* in Bellhouse.

Accordingly, at least because Bellhouse fails to teach or even suggest a method of modifying or manipulating body tissue by forming at least one microconduit therein that includes scissioning the tissue with the impinging microparticles, thereby forming a plurality of free microtissue particles, and thereby forming a microconduit, claim 1, as well as claim 2 which depends therefrom, represents allowable subject matter.

***Rejections Pursuant to 35 U.S.C. § 103(a)***

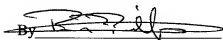
The Examiner rejects claims 21 and 22 pursuant to 35 U.S.C. § 103(a) as being obvious over Bellhouse in view of U.S. Patent No. 5,947,956 of Karell et al. ("Karell"). The Examiner argues that Bellhouse discloses the method substantially as claimed, but is silent on the microconduit being formed through nail tissue and administering at least one therapeutic molecule or ion into at least one microconduit through nail tissue. The Examiner relies on Karell to remedy the deficiencies of Bellhouse stated by the Examiner. Karell, which is directed to a microsurgical laser unit for performing surgery on nails, fails to teach or even suggest a method of modifying or manipulating body tissue by *forming at least one microconduit therein by scissioning tissue with impinging microparticles, thereby forming a plurality of free micro tissue particles, and thereby forming a microconduit*. At least because Karell fails to remedy the previously discussed deficiencies of Bellhouse, claims 21 and 22 represent allowable subject matter in view of both Bellhouse and Karell.

***Conclusion***

Applicants submit that all pending claims are in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Dated: September 23, 2008

Respectfully submitted,



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